REMARKS

I. Petition for Extension of Time

Applicants herewith petition the Commissioner for Patents to extend the time for response to the Office action mailed 3 March 2009 for one month from 3 June 2009 to 3 July 2009. Authorization is given to charge the extension of time fee of $130.00 (37 C.F.R. §1.136 and §1.17) to Deposit Account No. 23-1703. Any deficiency or overpayment should be charged or credited to the above numbered deposit account.

II. Disposition of Claims

Claims 20-37 are pending. The restriction and election of species requirements of record have been made final:

Group I: method claims 20-24 - administration of a P-CAB compound of formula I;

Group II: method claim 20 - administration of a P-CAB compound excluding formula I, i.e., excluding Group I;

Group III: method claims 32-33 - administration of soraprazan;

Group IV: method claim 32 - administration of a reversible ppi other than soraprazan, i.e., excluding Group III;

Group V: pharmaceutical formulation claims 25-31 - comprising a P-CAB compound of formula I;

Group VI: pharmaceutical formulation claims 25-27 - comprising a P-CAB compound excluding formula I, i.e., excluding Group V;

Group VII: pharmaceutical formulation claims 34-37 - comprising soraprazan; and

Group VIII: pharmaceutical formulation claims 25-27 - comprising a reversible ppi other than soraprazan, i.e., excluding Group VII.

In response to the restriction requirement, Applicants elected Group I ***with traverse***. In response to the election of species requirement, Applicants elected ***with traverse*** the second recited compound of claim 23: 2,3-dimethyl-8-(2,6-dimethylbenzylamino)-N-hydroxyethyl-imidazo[1,2-a]pyridine-6-carboxamide as a free base, i.e., neither as a hydrochloride salt or mesylate salt. Claims 20-23 of Group I read on the elected species.

Claims 24-37 have been withdrawn from consideration and claims 20-23 have been examined and are rejected.

III. Claim Rejections – 35 U.S.C. §103

Claims 20-23 are rejected under 35 U.S.C. §103(a) as being unpatentable in view of WO 99/55706 ("Amin") in combination with the publication to Harding, Susan M., "Nocturnal Asthma: Role of Nocturnal Gastroesophageal Reflux", Chronobiology International, 16(5), 641-662 (1999) ("Harding") or Carr, M.M. et al., "Severe non-obstructive sleep disturbance as an initial presentation of gastroesophageal reflux disease", Int. J. Pediatr. Otorhinolaryngol., 51 (1999) 115-120 ("Carr").

a. The claimed invention

The claimed invention is directed to the treatment of sleep disturbance due to silent gastroesophageal reflux ("GERD"). As defined by the specification at paragraph [0009] of the published patent application No. 2008/0280944, a patient suffering from silent GERD does not experience heartburn symptoms or other typical reflux symptoms, e.g., regurgitation. Rather, the target population of the claimed method includes patients having disrupted or fragmented sleep in response to a reflux event which the patient may or may not recall having had. Surprisingly, Applicants have found that the reflux of acidic contents into the esophagus causes arousals or awakenings even if the reflux episode is not associated with typical GERD symptoms. The patient suffers reduced sleep quality, productivity and quality of life.

b. The claimed invention is patentable over the cited art.

On page 6 of the Office Action, the Examiner alleges that the primary reference to Amin discloses imidazo pyridine compounds of the same formula as formula I of claim 21. The Examiner acknowledges, however, that Amin does not teach a method of treating the target population of the claimed invention, i.e., patient having a sleep disturbance due to silent GERD. For this purpose, the Examiner combines Amin with Harding or Carr in support of the obviousness rejection. As discussed below, each of Harding and Carr fails to overcome the acknowledged deficiency of Amin to suggest the claimed invention.

1. Harding

In contrast to the target population of the claimed method, the target population of Harding is asthmatics. In this regard, the Abstract of Harding expressly states that GERD is common in people with asthma. Thus, in view of the recognized relationship between GERD

and asthma, it is documented in the public domain that doctors will look at GERD as the cause of asthma, for example, when:

- asthma begins in adulthood, called adult-onset asthma;
- asthma symptoms get worse after a meal, after exercise, at night or after lying down; or
- asthma doesn't respond to the standard asthma treatments.

(See http://www.webmd.com/asthma/guide/heartburn-asthma)

Therefore, in certain cases, asthma is diagnosed and treated as a symptom of GERD. In such cases, the patient population would not fit the target population of the claimed method, i.e., patients who do not experience typical GERD symptoms, e.g., asthma. Accordingly, Harding fails to overcome the deficiency of the primary reference to Amin to suggest the claimed invention.

2. Carr

On page 7 of the Office Action, the Examiner states that Carr discloses the case of a child displaying atypical symptoms of GERD. Applicants respectfully disagree.

Although Carr mentions on the left-column on page 116 that GERD is sometimes "silent", the pediatric patient discussed by Carr unequivocally manifested several typical symptoms of GERD but, unfortunately, was initially misdiagnosed. Some of the child's symptoms included: coughing (p. 116), chronic hoarseness (p. 116), halitosis (p. 117) and emesis, i.e., vomiting (p. 117). These same symptoms are recognized in the art as typical GERD symptoms:

- a sore, raw throat or hoarse voice
- a dry cough
- bad breath

(See http://kidshealth.org/teen/diseases_conditions/digestive/gerd.html#)

Furthermore, vomiting is recognized as the most common symptom of GERD in infants. (See http://www.webgerd.com/GerdInInfants.htm). Thus, the pediatric patient of the case study discussed by Carr does not fit the target patient population of the claimed method, i.e., patients who do not experience typical GERD symptoms, e.g, coughing, hoarseness, halitosis,

vomiting, etc. Even Carr recognized that the pediatric patient was misdiagnosed. Accordingly, Carr fails to overcome the deficiency of the primary reference to Amin to suggest the claimed invention.

For all of the foregoing reasons, withdrawal of the §103 rejections is respectfully requested

IV. Claim Rejections – Double Patenting

Claims 20-23 are *provisionally* rejected for obviousness-type double patenting in view of claims 4-6 of co-pending U.S. Patent Application Serial Nos. 11/912,954 (the "'954 application") in view of Amin and Carr.

Applicants will respond to the provisional rejection with respect to the '954 application at such time that a patent for the reference application has been granted. Page 8 of the Office Action expressly states that the rejection is a *"**provisional** obviousness-type double patenting rejection". Applicants submit that it is the pendency of the allegedly conflicting claims that is the determining factor of the provisional nature of the rejection. It would be prejudicial to require Applicants to amend the claims of either the instant application or the allegedly conflicting application to overcome a provisional double-patenting rejection when neither of the two applications is deemed by the respective Examiner to be allowable. As no monopoly has been granted to Applicants, it is unfair to require Applicants to address a hypothetical double-patenting situation which may, in fact, never result.

In this regard, Applicant refers to MPEP §804(I)(B) and §804(I)(B)(1). These sections discuss provisional double-patenting issues between co-pending applications. These sections do not state than Applicant is required to amend his application to overcome a provisional double-patenting rejection. Rather, MPEP §804(I)(B) and §804(I)(B)(1) put the burden on the Examiner to make an Applicant aware of a ***potential*** double patenting problem and to continue to make the provisional double patenting rejection as long as there are conflicting claims in more than one application. Applicant is permitted to maintain the allegedly conflicting claims in both applications until one of the applications issues as a patent. At that time, Applicant would have to address a formal double-patenting rejection in the pending application in view of the issued patent.

In conclusion, the Office Action itself provides that the rejection is provisional. Furthermore, it is the Examiner who may maintain the rejection until such time that the double patenting rejection is the only remaining rejection. There is no obligation on the Applicant at this time. As neither the instant application nor the allegedly conflicting application has matured into a patent, Applicant submits that no further action is required at this time to address the provisional obviousness-type double-patenting rejection.

CONCLUSION

Applicants have made a good faith attempt to respond to the Office Action. Claims 20-23 are directed to patentable subject matter. Accordingly, Applicants request reconsideration and allowance of the claims.

Any fee due in connection with this communication should be charged to Deposit Account No. 23-1703.

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Respectfully submitted,

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